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EXAMINER	
MARVICH, MARIA	

ART UNIT	PAPER NUMBER
1633	

NOTIFICATION DATE	DELIVERY MODE
10/05/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/726,615	RANGNEKAR, VIVEK M.	
	Examiner	Art Unit	
	Maria B. Marvich, PhD	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *3-5 and 7-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,6 and 24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-24 are pending in this application. Claims 3-5 and 7-23 have been withdrawn from examination. Claims 1, 2, 6 and 24 are pending in the instant action. This action is in response to an amendment filed 7/11/07.

This application contains claims 3, 5 and 7-23 drawn to an invention nonelected with traverse in the reply filed 11/3/06. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Objections

Claim 1 is objected to because of the following informalities: Claim 1 recites that tumors are resistant to Par-4, which applicants explain in the amendment filed 7/11/07 means that the tumor is resistant to apoptosis by Par-4. It would be remedial to insert this phrase into the claims to provide clarity, as it is clear that tumors can be resistant to the action of a protein but not to the protein itself.

As well, claim 1 requires the word --at-- prior to "least one amino acid" in line 2 and an article prior to "naturally produced Par-4" in line 3. As to the later, if the naturally produced Par-4 is the same as the precursor then it would be remedial to recite --the naturally produced precursor Par-4--. If the naturally produced Par-4 were any Par-4 that serves as a reference sequence it would be remedial to insert the article --a--.

Appropriate correction is required.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 2 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is vague and indefinite in that the metes and bounds of "1-204, 137-221, 137-213, 137-198 and 137-195" are unclear. Applicants argue on pages 6-7 of the amendment filed 7/11/07 that Par-4 stands for rat prostate apoptosis response-4 protein and the numbers "1-204, 137-221, 137-213, 137-198 and 137-195" indicates numbered amino acids forming fragments of the protein. However, this statement does not clarify to what the reference sequence is, as the specification does not identify the sequences from which these fragments are obtained. And without such a reference sequence, the ability to determine the metes and bounds of the fragments are. As well, the claim language is unclear and would be improved by reciting -- modified Par-4 of claim 1 consisting of a fragment of wild-type rat Par-4 selected from the group consisting of fragments 1-204, 137-221, 137-213, 137-198 and 137-195--. However, this does not clarify what the fragments 1-204, 137-221, 137-213, 137-198 and 137-195 actually are.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The limitation that "the modified Par-4 is a Par-4s" has been added to claim. Applicant has not indicated where support for this limitation is found. The examiner has been unable to find support in the originally filed specification for the term "Par-4s". The term appears to be a designation of a specific type of Par-4 mutant but as this term is not identified in the specification it is not clear to what the designation refers. Therefore, the limitation of is impermissible NEW MATTER.

Claims 1, 2, 6 and 24 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated modified rat Par-4 wherein the modified Par-4 is selected from the group consisting of fragments 1-204, 137-221, 137-213, 137-198 and 137-195 or a modified Par-4 comprising a substitution in rat Par-4 mature polypeptide wherein the modified Par-4 does not comprise a substitution in a region of rat Par-4 selected from the group

consisting of fragments 1-204, 137-221, 137-213, 137-198 and 137-195 does not reasonably provide enablement for any other embodiment. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. **The claims have been scoped to enabled subject matter based upon applicants' arguments.**

The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The test of enablement is whether one skilled in the art could make and use the claimed invention from the disclosures in the patent coupled with information known in the art without undue experimentation (*United States v. Telectronics, Inc.*, 8 USPQ2d 1217 (Fed. Cir. 1988)). whether undue experimentation is required is not based on a single factor but is rather a conclusion reached by weighing many factors (See *Ex parte Forman*, 230 USPQ 546 (Bd. Pat. App. & Inter, 1986) and In *re Wands*, 8USPQ2d 1400 (Fed. Cir. 1988); these factors include the following:

1) **Nature of invention**. The claims are drawn to a modified Par-4 comprising at least one substitution wherein the modified Par-4 is effective in reducing the size of tumors resistant to Par-4. As well the modified Par-4 "comprises" a mutant of Par-4 that is selected from 1-204, 137-221, 137-213, 137-198 and 137-195. Hence, these mutants have at least one substitution and is a fragment of Par-4. Finally, the claims are drawn to an isolated peptide comprising at least 5 amino acids comprising *a* sequence encoded by the polynucleotides encoding 1-204, 137-

221, 137-213, 137-198 and 137-195. The invention utilizes disciplines of molecular biology and protein chemistry.

2) **Scope of the invention**. The scope of the claims is very broad in that they are drawn to any modified Par-4 sequence that is Par-4S whereas Par-4S is not defined or specifically described in the specification. Hence, the claims are drawn to *any* modified Par-4 sequence wherein the sequence comprises *any* number of substitutions in *any* precursor Par-4 whereas the specification does not disclose any precursor Par-4 sequences. As well, the claims recite that the substitution is "in at least one position of naturally produced Par-4", wherein this is *any* naturally produced Par-4. However, the relationship between naturally produced Par-4 and precursor Par-4 is not clear. The claims are also drawn to an isolated peptide comprising at least 5 amino acids comprising *a* sequence encoded by the polynucleotides encoding 1-204, 137-221, 137-213, 137-198 and 137-195 wherein *a* polynucleotide can be as little as one dinucleotide.

3) **Number of working examples and guidance**. The specification teaches that Par-4 comprises a unique core domain that is 59 amino acids that comprises a nuclear localization domain and two phosphorylation sites that are localized to between position 137 and 195 of "the wild-type Par-4" protein. This region contains a nuclear localization sequence, which is sufficient and necessary to induce apoptosis in Par-4 resistant cancer cells as well as Gas pro death pathway activation. Par-4 mutants deleted of the nuclear localization signal at 147-153 did not enter the nucleus and did not lead to apoptosis of PC3 cells. And Par-4 mutants 1-204, 137-221, 137-213, 137-198 and 137-195 lead to apoptosis in transient transfections in several cancer cells but not the corresponding normal cells. A panel of androgen dependent or independent prostate cancer cells, immortalized cells and primary cells were tested. Apoptosis was induced

in androgen dependent and independent cells but not the normal or immortalized cells (see Table 1 and 2). As well applicants disclose that fragments 5 amino acids or greater can be used to assemble a functional full polypeptide (see e.g. bridging ¶page 26-27). Structurally, the nomenclature 1-204, 137-221, 137-213, 137-198 and 137-195 translates into peptides that have been deleted of all but a core region applicants have identified as a death domain. Actual substitution of any amino acids within Par-4 are not so described in the specification.

4) **State of Art**. A review of the art demonstrates that the ability to *de novo* protein model is not routine but requires vast computation skills (see Protein structure prediction, page 2, first paragraph). This article also teaches that prediction methods that rely on comparative protein modeling allow similar domains or structures to allow identification of three-dimensional models (see Protein structure prediction, page 2, first paragraph). However, as demonstrated by Smith et al, even a single mutation can greatly effect even simple structural formations of the resultant protein. This is explained in the review titled Tertiary structure that teaches mutations in genes encoding proteins can result in degradation or lack of transport or aggregation into insoluble deposits of the resulting protein (begin page 1, last paragraph). A particular protein sequence determines the protein's structural, and functional properties, and a predictability of a representative number of claimed polypeptide sequences that display noteworthy biological properties requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e., expectedly intolerant to modification), and detailed knowledge of the ways in which a protein's structure relates to its functional usefulness (see Tertiary structure, Protein structure prediction and Smith

et al). Therefore, the ability to predict *a priori* which sequences that are identified following hybridization will meet a particular goal must be considered to be poorly developed.

5) **Unpredictability of the art**. The enablement of the instant invention has been assessed in light of the specification and the prior art available at the time of filing. "However, claims reading on significant numbers of inoperative embodiments would render claims non-enabled when the specification does not clearly identify the operative embodiments and undue experimentation is involved in determining those that are operative. Atlas Powder Co. v. E.I. duPont de Nemours & Co., 750 F.2d 1569, 1577, 224 USPQ 409, 414 (Fed. Cir. 1984); In re Cook, 439 F.2d 730, 735, 169 USPQ 298, 302 (CCPA 1971). (see MPEP 2164.08(b). In the instant case, there are multiple inoperative embodiments when considering the broad nature of the claims as broadly drawn to any Par-4 containing peptide listed below.

1) Applicants reference a broad and diverse genus of Par-4 protein whose modification may or may not result in effectiveness is reducing the size of tumors resistant to Par-4. Furthermore, the substitutions are said to be in the amino acid sequence of a precursor Par-4 sequence, which exacerbates the ability to identify the sequence intended as Par-4. By referencing "a precursor Par-4", the reference sequence becomes even more confusing. The art teaches a variety of diverse proteins known as Par-4 proteins ranging from AAD45355 from *C. elegans* that is a 617 amino acids putative serine-threonine kinase to multiple human proteins. Three proteins from *Homo sapiens* identified as Par-4 include BAC99030 (121 amino acid) prostate apoptosis response protein, NP_002574 (340 amino acids) and Q62627 (332 amino acid) the later two proteins listed as PRKC apoptosis proteins. Fewer sequences known as "precursor Par-4' are identified. Given the recitation in claim 2 to specific deletion mutants, 1-

204, 137-221, 137-213, 137-198 and 137-195, without providing a reference sequence engenders a level of difficulty in identifying the proper "core" that is meant to be contained within 1-204, 137-221, 137-213, 137-198 and 137-195. These positions become artificial landmarks without an indication as to what sequences can or are contained within them. In light of the art at the time of filing, the instant invention would require undue experimentation to identify modified Par-4 proteins as broadly recited.

2) Applicants refer broadly to a Par-4 that is modified. In base claim 1, the modified Par-4 appears to be drawn to a protein comprising a substitution in its amino acid sequence as compared to precursor Par-4 sequence such that modified Par-4 is effective in reducing the size of tumors resistant to Par-4. Thus the claims recite broadly that the modified Par-4 comprises *any* substitution of any amino acid residue in *any* precursor Par-4 sequence. By recitation of at least one substitution a broad and diverse genus of peptides with substitutions of as little as one amino acids to substitution of multiple amino acids within the protein are encompassed. However, the efficacy of the peptide is based upon its pro-apoptotic activity in cancer cells, which is described as the result of deletion of sequences outside of the critical "death domain". Applicants do not teach any substitutions in Par-4 nor do applicants provide structural requirements other then the core domain such that a person of skill in the art would know what amino acids can be substituted in any Par-4 protein. Hence, it would require undue experimentation to determine those amino acids in the precursor protein of any Par-4 protein that can be substituted in order to lead to reduction of tumor size of Par-4 resistant tumors given the lack of guidance in the specification.

3) Finally, in claim 6, applicants claim a genus of peptides that are said to he at least five amino acids long and comprises a sequence encode by any of the 1-204, 137-221, 137-213, 137-198 and 137-195 mutant polynucleotide sequences. Thus a genus of peptides are recited that are only limited by comprising at least 5 amino acids in which a sequence is encode by a nucleic acid contained in a Par-4 mutant sequence. The specification discloses that such a polypeptide can be used in combination with other peptides to form a fully functional Par-4 peptide. As so disclosed, only fragments completely homologous to Par-4 are consistent with the claimed invention have an enabled use.

6) **Summary**. Given the broad nature of the recited modified Par-4 proteins and the unknown nature of the amino acid sequence and the unknown numbers of substitutions, the invention has a high level of unpredictability. The specification does not disclose the reference sequence. As well, while the claims recite a Par-4 comprising substitutions of amino acids residues, the specification does not disclose any modifications of Par-4 that are the result of substitution. Rather, the specification discloses a Par-4 peptide that has been modified to induce apoptosis in tumors resistant to Par-4 are the result of deletion of amino acids surrounding a core sequence of "137-195" which particularly must embrace deletions of the C-terminus leucine-fingers. Hence, the specification does not disclose any substitutions that result in peptides effective against Par-4 resistant tumors. Rather, the specification only discloses that deletion of the C-terminus leucine-fingers have an enabled use in inducing apoptosis in Par-4 resistant tumors. Exacerbating the unpredictability of identifying substitutions is the lack of disclosure of the reference sequence for mutants 1-204, 137-221, 137-213, 137-198 and 137-195. As the claims do not identify the source of the Par-4 peptide, it is not clear to what sequences 1-204,

137-221, 137-213, 137-198 and 137-195 correspond. While the specification teaches that the particular Par-4 peptide of the instant invention has 332 amino acids and the modified peptide must comprise 1-204, 137-221, 137-213, 137-198 and 137-195, it is highly unpredictable that the sequences corresponding to 1-204, 137-221, 137-213, 137-198 and 137-195 can be identified for any Par-4 peptide given the wide and variable sequences known as Par-4. Even if the sequence could be said to be limited to Q62627, which is 332 amino acids, and this sequence comprises the "death domain" within amino acids 1-204, 137-221, 137-213, 137-198 and 137-195, the claims are drawn to a modified Par-4 in which at least one amino acid is substituted. Modification of even as little as one amino acid has the potential to effect the function of the protein as taught by Tertiary structure, Protein structure prediction and Smith et al especially as the specification does not teach the structural properties of Par-4 amino acids that can be substituted. In view of predictability of the art to which the invention pertains and the lack of guidance and the inability to predict sequences required: undue experimentation would be required to practice the claimed methods with reasonable expectation of success, absent a specific and detailed description in the specification. Given the above analysis of the factors which the courts have determined are critical in determining whether a claimed invention is enabled, it must be concluded that the skilled artisan would have had to have conducted undue unpredictable experimentation in order to practice the claimed invention.

Response to Argument

Applicants traverse the claim rejections under 35 U.S.C. 112, first paragraph on page 7 of the amendment filed 7/11/07. Applicants' arguments filed 7/11/07 have been fully considered

but they are not persuasive. The broad nature of the recited peptides coupled with the lack of guidance in the specification makes identifying modified Par-4 peptides that reduce tumor size highly unpredictable. Claim 1 recites that the modified Par-4 comprises "a substitution of at least one amino acid residue in the amino acid sequence of naturally produced Par-4". Dependent from this is claim 2, which recites that the modified Par-4 is acids 1-204, 137-221, 137-213, 137-198 and 137-195. First, the claims as recited are broadly drawn to any modified Par-4 that is the result of substitution of at least one amino acid of precursor Par-4 when compared to any naturally occurring Par-4. However, the modified Par-4 is also Par-4s but the specification does not teach what Par-4s is. This is exacerbated by the lack of disclosure as to the source or sequence of precursor Par-4 and naturally produced Par-4. Finally, the fragments of claim 2 do not appear to be obtained from precursor Par-4 in which at least one substitution has occurred in naturally occurring Par-4.

Applicants argue that direct support for the rat Par-4 region is said to be found in teachings in the specification. The section (¶ 0040 of the published application) applicants' reference teaches, "The Par-4 gene, first identified by the inventors (see Sells et al., 1994) in prostate cancer cells undergoing apoptosis, encodes a proapoptotic protein that is remarkably effective in inducing cancer cell apoptosis and tumor regression in animal models." Applicants argue that these teachings demonstrate that rat Par-4 is the target molecule to produce modified Par-4. However, these teachings do not explicitly provide any indication of sequence, source or organism from which Par-4 is obtained. Rather, the claims are drawn to *any* modified Par-4 that is Par-4s and the specification does not limit the peptide to that from Rat. While these teachings from the specification may teach that Par-4 was identified from rat, there is no indication that

this means the claims are thus limited to rat. In fact, equal reference is made to human, rat and mouse Par-4 in the specification (¶ 0052 and 0103 of the published application). If applicants would like to limit the claims to rat Par-4, the claims would have to reflect this. As well, a copy of the Sells et al., 1994 is encouraged. "The duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by §§ 1.97(b)-(d) and 1.98."

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 6 and 24 stand rejected under 35 U.S.C. 102(b) as being anticipated by Guo et al (Nature Medicine, 1998, pages 957-962; see entire document).

Guo et al teach Par-4 protein that comprises substitutions in amino acid sequences as compared to full length Par-4 in that sequences comprising for example termination signals are replaced with leucine zipper sequences (Par-4-Leu-Zip) or substitution of the C-terminal region

for termination sequences (Par-4-Δleu-Zip), see figure 3. This modified Par-4 peptide exhibits effectiveness in inducing apoptosis of cells previously non-apoptotic in the presence of Par-4 absent inducer as evidenced in figure 3 as recited in claim 1. These peptides comprise at least five amino acids with several sequences encoded by the nucleic acid of 1-204 mutants as recited in claim 6. While claim 24 recites that the pharmaceutical composition comprises a Par-4 mutant protein sequence of claim 3, claim 3 is drawn to nucleic acid. Thus claim 24 is interpreted to intend that the nucleic acid sequences of claim 3 encode the Par-4 mutants included in the pharmaceutical composition. Based upon this interpretation and given the broadest possible interpretation of a carrier, the teachings of Guo et al teach that the Par-4 mutants were delivered with Lipofectamine (see e.g. page 959, col 2, ¶ 1) can be said to read on a composition of Par-4 in acceptable diluent and carrier as recited in claim 24.

Claim 6 stands rejected under 35 U.S.C. 102(e) as being anticipated by Darrow et al (US 2006/0141451; see entire document).

Darrow et al teach a chimeric peptide, which comprises substitution of one Par-4 sequence for another with the goal of combined functions of the combined domains

Darrow et al teach peptides with at least 5 amino acids in which the peptide comprises at least one sequence that is also found in the mutant Par-4 sequences recited as 1-204, 137-221, 137-213, 137-198 and 137-195 given that as shown in figure 2 and embraced in the specification at for example ¶ 0009 which discloses a fragment of at least 15 amino acids corresponding to amino acids 219 to 243 of SEQ ID NO:3 (Par-4), the sequences comprise Par-4 sequences as recited in claim 6.

Response to Argument

Applicants traverse the claim rejections under 35 U.S.C. 102 on pages 7 and 8 of the amendment filed 7/11/07. Applicants' arguments filed 7/11/07 have been fully considered but they are not persuasive. Applicants argue that the modified Par-4 molecules of Guo et al do not produce apoptosis and are not used in any testing of human cancer cells. With these arguments, applicants rely on limitations that are not part of the instant claims. The claims are not limited to a Par-4 protein that produces apoptosis or to one that is involved in human testing. As to claim 6, applicants argue that Darrow does not teach prostate apoptosis peptide-4. Again, applicant relies on limitations that are not part of the instant claims. Rather, claim 6 is drawn to an isolated peptide. This peptide need not be prostate apoptosis peptide-4 but simply "a sequence encoded by a nucleic acid contained in prostate apoptosis peptide 4 regions". By recitation of "a sequence encoded by a nucleic acid", the peptide only need have a dinucleotide in common with these regions.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B. Marvich, PhD whose telephone number is (571)-272-0774. The examiner can normally be reached on M-F (7:00-4:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, PhD can be reached on (571)-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Maria B Marvich, PhD
Examiner
Art Unit 1633

Joe Woitach
AU1633